Memorandum

Date: June 21, 2004

From: Division of Petition Review (HFS-265)
Chemistry Review Group

Subject: **FAP 3A4743** (MATS #1142, M2.2): Alcide Corporation. Acidified solutions of sodium chlorite in processing waters intended for use on seafood or freshwater fish. Submission dated 5/28/04.

To: Division of Petition Review
Regulatory Review Group II
Attn: M. Honigfort, Ph.D.

In the chemistry memorandum dated 4/13/04, we noted outstanding chemistry-related deficiencies regarding the subject petition. Many of the chemistry-related concerns were dependent upon the resolution of issues regarding the efficacy of acidified sodium chlorite (ASC) solutions under the intended conditions of use. These issues were communicated to Alcide in a letter dated 5/5/04, and discussed in a subsequent meeting with Alcide on 5/14/04. Alcide responded to our requests for additional information in the subject amendment dated 5/28/04. The chemistry-related issues are discussed below.

Conditions of Use, Residues, and Exposure

In the chemistry memorandum dated 4/13/04, we determined that a 24-hour holding period was necessary for all ASC-treated seafood. In addition, we indicated that the data provided by Alcide supported a maximum treatment time of 30 seconds. The use of a 24-hour hold in connection with a maximum treatment time of 30 seconds would eliminate the concern for chlorite and chlorate residues on seafood intended to be consumed raw. As noted in the chemistry memorandum, there is no concern regarding chlorite or chlorate residues on seafood that will be cooked prior to consumption, because cooking will convert any remaining chlorite and chlorate residues to chloride.

The letter to Alcide dated 5/5/04 indicated that additional microbiology testing could be necessary to determine the appropriate treatment times for the specified conditions of use (i.e., pH 2.3-2.9, 4-22 °C). It was further noted that if longer treatment times were required, additional data for chlorite and chlorate residues on treated seafood should be provided. These requests would address our main concern regarding chlorite and chlorate levels on treated seafood that would be consumed raw (i.e., sushi).

In their submission dated 5/28/04, Alcide agreed to exclude the treatment of seafood that will be consumed raw from the intended conditions of use, and limit the use of ASC solutions to seafood that must be cooked prior to human consumption. In addition, Alcide noted that the treatment time for seafood would range from 30 seconds to 300 seconds. Because Alcide has indicated that all treated seafood will be cooked prior to consumption, and cooking will remove

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any remaining chlorite and chlorate residues, we have no concern regarding the longer treatment times. In addition, the limitation of the use of ASC solutions to seafood that will be cooked removes the need for a 24-hour hold of treated seafood prior to human consumption. Therefore, this requirement has been removed from the intended conditions of use.

We have no further questions regarding the conditions of use, chlorite and chlorate residual levels, and intake of chlorite and chlorate.

Proposed Regulation

In their most recent submission dated 5/28/04, Alcide proposed the following language for the regulation:

> (d)(2) The additive is intended for single-use application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross-contamination during the harvesting, handling, heading, evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in a chlorite concentration of 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to human consumption.

The proposed language is acceptable.

Draft Technical Bulletin

In their submission dated 1/7/04, Alcide provided a draft technical bulletin that would be included with every drum of product sold. This bulletin contained information on the conditions of use for all of the currently-approved and newly-proposed uses of ASC solutions. This bulletin indicated that ASC solutions should be applied to seafood for a minimum of 30 seconds. However, the residue data provided by the petitioner supported the use of ASC solutions for a maximum of 30 seconds on seafood.

After discussions with Alcide on 5/14/04, it was agreed that longer treatment times could be used if the seafood was cooked prior to human consumption. This would eliminate the concern for any remaining chlorite and chlorate residues on the surface of treated seafood.

In their submission dated 5/28/04, Alcide provided a revised technical bulletin that supersedes the draft technical bulletin in the 1/7/04 submission. The revised technical bulletin indicates that all treated seafood must be cooked prior to human consumption and that treatment times for seafood range from 30 seconds to 300 seconds. In addition, the bulletin states that adjustment in treatment times may be necessary with changes in temperature. Finally, the requirement for a 24-hour hold prior to human consumption has been removed from the technical bulletin.

The draft technical bulletin is acceptable. We have no further questions.

Conclusion

Alcide has provided responses to the chemistry-related deficiencies identified in our memorandum dated 4/13/04. We have no further questions. The petition is suitable for regulation with respect to the chemistry-related information.

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